UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JUDITH A. REDD,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 4:13CV2228 CDP
	)	
DePUY ORTHOPAEDICS, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

Plaintiff Judith Redd underwent a hip replacement using a prosthesis manufactured by defendant DePuy Orthopaedics, Inc. Approximately four years later, the replacement failed and Redd was diagnosed with a broken femoral component (stem) of her prosthesis. Redd has sued DePuy, alleging that the failure was caused by the prosthesis's defects and DePuy's failure to warn of the risks. She brings four state common law claims under negligence and strict liability theories.

This action is now before me on DePuy's Rule 12(b)(6) motion to dismiss. DePuy argues that Redd's claims are preempted by the 1976 Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act. It also argues that even if the claims are not preempted, Redd has failed to state a plausible claim for relief. Because I find that the claims are not preempted and that they meet federal pleading requirements, I will deny DePuy's motion.

I. Motion to Dismiss Standard

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint. When considering a 12(b)(6) motion, the court assumes the factual allegations of a complaint are true and construes them in favor of the plaintiff. *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989).

Rule 8(a)(2), Fed. R. Civ. P., provides that a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." In *Bell Atlantic Corp. v. Twombly*, the Supreme Court clarified that Rule 8(a)(2) requires complaints to contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." 550 U.S. 544, 555 (2007); *accord Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). Specifically, to survive a motion to dismiss, a complaint must contain enough factual allegations, accepted as true, to state a claim for relief "that is plausible on its face." *Twombly*, 550 U.S. at 570. The issue in considering such a motion is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to present evidence in support of the claim. *See Neitzke*, 490 U.S. at 327.

II. Background[1]

DePuy designed, manufactured, and sold the AML Total Hip System, including the AML Small Stature stem. Redd's left hip was replaced with the System in April 2008. Approximately four years later, she was diagnosed with a broken stem, which had caused her hip replacement to fail. She claims that the stem was subject to premature and sudden fatigue fracture because the alloy used had inadequately low fatigue strength and limited ductility and because the manufacturing process did not adequately anneal the alloy. She brings the following four claims under Missouri common law: Strict Liability – Product Defect; Strict Liability – Failure to Warn; Negligence – Product Defect; and Negligence – Failure to Warn.[2]

III. The Medical Device Amendments

In 1976, Congress passed the Medical Device Amendments to the Food, Drug and Cosmetic Act. *See* 21 U.S.C. § 360c *et seq.* The amendments authorized the FDA to "regulate the safety and effectiveness of medical devices." *In re Medtronic, Inc.*, 623 F.3d 1200, 1203 (8th Cir. 2010). Through the amendments, which were a response to proliferation (and frequent failure) of medical devices entering the market, Congress "swept back some state obligations and imposed a regime of

[1] The facts that follow are taken from the allegations set out in Redd's complaint. They are considered true for the purpose of this Memorandum and Order. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009); *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989).

[2] The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332.

detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) (MDA was enacted in "response to mounting consumer and regulatory concern").

The MDA classifies medical devices into three groups (Classes I, II, and III) based on the degree of risk they pose. In general, Class III devices – as the most dangerous – are subject to the highest level of scrutiny by the FDA. This manifests in a rigorous, comprehensive inquiry called "premarket approval." *See Lohr*, 518 U.S. at 477 (noting that it takes the FDA an average of 1,200 hours to review an application for premarket approval). However, through the MDA, Congress also provided an alternative route to market for all medical devices, including Class III devices. If the FDA deems a medical device to be "substantially equivalent" to a device already on the market,[3] the FDA may approve its sale through a process known as "premarket notification" or the "§ 510(k) process." *See Lohr*, 518 U.S. at 478–80 (noting that a § 510(k) review takes an average of 20 hours). Most Class III devices now being sold have entered the market through the abbreviated § 510(k) process rather than the more demanding premarket approval process. *Id.* at 479.

[3] Under the MDA, devices marketed before 1976 are grandfathered "until such time as the FDA initiates and completes" premarket approval. *Id.* (citing 21 U.S.C. § 360e(b)(1)(A); 21 CFR § 814.1(c)(1)). Therefore, a new Class III device may also be marketed if it is substantially equivalent to a grandfathered device, though neither has undergone premarket approval.

The MDA also expressly preempts certain state laws. Subject to some unrelated exceptions, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

21 U.S.C. § 360k(a).

The Supreme Court has articulated a two-part test for applying the express preemption principles codified in Section 360k of the MDA. *See Riegel*, 552 U.S. at 321–22. The test requires the court to examine the particular federal laws and regulations applicable to the device in question and compare them to the state claims the plaintiff wishes to bring. First, a court must determine whether "the Federal Government has established requirements" applicable to a particular device. Second, the court must determine whether a plaintiff's claims "are based upon [state] requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to safety and effectiveness." *Id.*

The contours of this test are further illuminated by the Supreme Court's holdings in *Lohr* and *Riegel*. In *Lohr*, a divided Supreme Court held that the petitioner's state common law claims concerning a device brought to market through

the § 510(k) process were not preempted under Section 360k. *Id.* at 481, 494–95. Although the device at issue – a pacemaker lead – was categorized as Class III, it was subject only to the FDA's "general controls," the lowest and least specific of the three levels of oversight. The Court held that neither the § 510(k) process nor the continuing "general controls" were a device-specific federal "requirement" that could trigger Section 360k preemption. *Id.* at 493–94; *see also Riegel*, 552 U.S. at 322. However, five justices did find that common law claims for negligence and strict liability imposed state "requirements" and would therefore be preempted had there been federal requirements to override them. *See id.* at 512 (opinion of O'Connor, J., joined by Rehnquist, C. J., and Scalia and Thomas, JJ.); *id.* at 503–05 (opinion of Breyer, J., concurring in part and concurring in the judgment).

In *Riegel*, the Court held that similar state common law claims *were* preempted when they involved devices that had undergone the rigorous premarket approval process. 552 U.S. at 322–25. Unlike the brief § 510(k) process, premarket approval was "specific to individual devices" and "focused on safety, not equivalence." *Id.* at 323. Therefore, premarket approval was a federal "requirement" that met the first prong of the test for Section 360k preemption. Turning to the second prong of the Section 360k preemption test, the *Riegel* Court held – like the *Lohr* majority – that "[a]bsent other indication, reference to a State's 'requirements' includes its common-

law duties." *Id.* at 324. Addressing the Section 360k language that only state requirements "with respect to devices" are preempted, the *Riegel* Court held that nothing in the MDA "suggests that the preempted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general." *Id.* at 328.

In addition to its holdings in *Lohr* and *Riegel*, the United States Supreme Court weighed in on the preemptive effects of the MDA a third time in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In that case, the Court construed § 337(a) of the MDA – which provides that all actions to enforce FDA requirements "shall be by and in the name of the United States" – "as barring suits by private litigants 'for noncompliance with the medical device provisions.'" *In re Medtronic*, 623 F.3d at 1204 (quoting *Buckman*, 531 U.S. at 349 n.4). The Eighth Circuit has read *Buckman* and *Riegel* together to create only a "narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Id.* As such, a plaintiff "must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

IV. Express Preemption: Whether The Hip System Is Subject to Federal "Requirements"

The first question in this case is whether DePuy's AML Total Hip System, including its small stature stem, is subject to federal requirements that could expressly preempt Redd's claims. *See Riegel*, 553 U.S. at 322. Because the Hip System was brought to market through the § 510(k) process and is bound only by the FDA's general regulations, I find that it is not subject to any device-specific federal requirements that would have the effect of preempting Redd's claims.

The Hip System came to market through the § 510(k) process and is a Class II device.[4] A Class II device "cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(B). Class II devices are not required to undergo the rigorous premarket approval process, but can be subject to special controls, which may include "the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, . . . recommendations and other appropriate actions as the Secretary

[4] DePuy requests I take judicial notice that the AML hip stem at issue is a medical device subject to regulation by the U.S. Food and Drug Administration under the MDA. DePuy's memorandum in support of its motion to dismiss also cites to several FDA documents and web pages containing public records. "Generally, the Court must ignore materials that are outside of the pleadings, however, district courts may take judicial notice of public records and may thus consider them on a motion to dismiss." *Stahl v. U.S. Dept. of Agriculture*, 327 F.3d 697, 700 (8th Cir. 2003) *quoted in Blankenship v. Medtronic*, No. 4:13-CV-1087, 2014 WL 1226491, at *1 n. 1 (E.D. Mo. March 25, 2014). Accordingly, I will take judicial notice of documents that are public records.

deems necessary to provide [reasonable assurance of the safety and effectiveness of the device]." *Id.*

Defendant DePuy argues that the Hip System here is subject to certain special controls, which constitute federal "requirements" that preempt Redd's state common law claims. The two special controls Defendant DePuy references are a regulation specifying the material composition of the stem and a Class II Special Controls Guidance Document issued by the FDA.

Redd responds that the regulation contains only a "generic description and identification" of certain hip devices and "mandates nothing about the specifics of the annealing process or prevention of mid-shaft fractures." She argues that the Guidance Document does not specifically address her claims either, but rather, merely lays out a set of recommendations that, if followed, will "lead to a timely § 510(k) review and clearance." (Def.'s Ex. 4, Doc. 13-4, p. 1.) Redd contends that because neither the regulation nor the Document imposes any true obligation stricter than the § 510(k) substantial equivalence process, they are not federal "requirements." Therefore, Redd argues, *Lohr* controls and her claims are not preempted.

The regulation DePuy relies on does little more than identify characteristic features of the Hip System and other prostheses like it. It reads, in full:

> Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
>
> (a) Identification. A hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device has a femoral component made of a cobalt-chromium-molybdenum (Co–Cr–Mo) alloy or a titanium-aluminum-vanadium (Ti–6Al–4V) alloy and an acetabular component composed of an ultra-high molecular weight polyethylene articulating bearing surface fixed in a metal shell made of Co–Cr–Mo or Ti–6Al–4V. The femoral stem and acetabular shell have a porous coating made of, in the case of Co–Cr–Mo substrates, beads of the same alloy, and in the case of Ti–6Al–4V substrates, fibers of commercially pure titanium or Ti–6Al–4V alloy. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. The generic type of device has a design to achieve biological fixation to bone without the use of bone cement.
>
> (b) Classification. Class II.

58 Fed. Reg. 3227-01 (Jan. 8, 1993) (codified at 21 CFR § 888.3358). The identification or classification of the Total Hip System is not enough to trigger federal preemption. *See James v. Diva Int'l*, 803 F. Supp. 2d 945, 951 (S.D. Ind. 2011) (rejecting manufacturer's contention that a similar regulation identifying and classifying a menstrual cup was sufficient to preempt the plaintiff's state common law claims). Instead of containing device-specific "requirements" with which manufacturers must comply, this regulation is simply one of many contained in 21 CFR § 888 that "[set] forth the classification of orthopedic devices intended for

human use that are in commercial distribution." 21 CFR § 888.1(a) (2013). As the court in *James* noted, Defendant has not in any way shown that this type of generic identification and classification "is not generally required of each type of medical device that falls under the purview of the MDA." *James*, 803 F. Supp. 2d at 951. Therefore, I find that the regulation identified by DePuy is insufficient to preempt Redd's state law claims.

Turning to the Special Controls document identified by Defendant, I first note that its title is "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA." This title indicates the document provides special controls guidance for devices classified as "hip joint *metal/polymer constrained cemented or uncemented prosthesis*" (emphasis added). However, both DePuy and Redd agree that the device at issue in this litigation is classified under 21 CFR § 888.3358 as "hip joint *metal/polymer/metal semi-constrained porous-coated uncemented prosthesis*" (emphasis added). Similarly, DePuy has asserted that an October 19, 2001 letter from the FDA clearing the device at issue in this litigation for sale could be found at http://www.accessdata.fda.gov/cdrh_docs/pdf/K012364.pdf. The 510(k) Summary and FDA letter found at this web address reference the same device described in 21

CFR § 888.3358 and not the device named in the title of the Special Controls document.

Furthermore, a review of the CFR sections identifying and classifying other hip prostheses reveals that a separate regulation contains the identification and classification for the device named in the Special Controls document. 21 CFR § 888.3310 is titled "Hip joint metal/polymer constrained cemented or uncemented prosthesis." Subsection (b) of this regulation reads as follows:

> (b) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis."

In short, it appears that the Special Controls document cited by DePuy, while certainly providing guidance for a prosthetic hip device, does not provide guidance or requirements for the particular hip prosthesis that was implanted in Plaintiff Redd. DePuy has failed to point to any device-specific federal requirements applicable to the Hip System.

Just as in *Lohr*, the Hip System here was cleared for market through the §510(k) process as opposed to the rigorous PMA process and is apparently subject only to the FDA's "general controls." Therefore, the Hip System is not subject to any federal requirements, and the first prong of the express preemption test articulated in *Riegel* has not been met. *See Riegel*, 552 U.S. at 321-323. *See also Lohr*, 518 U.S. at

480, 492-494; *James*, 803 F.Supp. 2d 245 (no federal requirements existed where defendant failed to identify any special controls, performance standards, post-market surveillance or guidelines applicable to the particular Class II device at issue); *Elliott v. Smith & Nephew, Inc.*, No. 1:12cv0070 EJL, 2013 WL 1622659, at *4 (D. Idaho Apr. 15, 2013) ("[s]ince the §510(k) process does not impose specific federal requirements on a device, state law claims against devices subject only to premarket notification, rather than premarket approval, are not expressly preempted under the MDA"). DePuy's motion to dismiss on this point is denied.

V. Whether Plaintiff Redd Has Stated a Plausible Claim for Relief

DePuy also also argues that Redd's claims must be dismissed because she cannot satisfy the pleading requirements established under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 555 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Generally, Defendant DePuy argues that Plaintiff Redd's claims are insufficient because they allege bare legal conclusions without sufficient factual support. However, "*Twombly* and *Iqbal* did not abrogate the notice pleading standard of Rule 8(a)(2)." *Hamilton v. Palm*, 621 F.3d 816, 817-18 (8th Cir. 2010). Those decisions simply confirmed that Rule 8(a)(2) is satisfied "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

A. <u>The Strict Liability Claims.</u>

In Missouri, the theory of strict liability is broken down into liability for defective design and liability for failure to warn of an inherent danger in the product. These two theories have been codified pursuant to Mo. Rev. Stat. § 537.760. *Sperry v. Bauermeister, Inc*., 786 F. Supp. 1512, 1516 (E.D. Mo. 1992). According the statute, the elements of strict liability for defective design and failure to warn are as follows:

> (1) The defendant, wherever situated in the chain of commerce, transferred a product in the course of his business; and
> (2) The product was used in a manner reasonably anticipated; and
> (3) Either or both of the following:
> (a) The product was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use, and the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold; or
> (b) The product was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, and the plaintiff was damaged as a direct result of the product being sold without an adequate warning.

Mo. Rev. Stat. § 537.760.

The only issue before this Court at the motion to dismiss stage is whether Plaintiff has alleged enough facts "to raise a right to relief above the speculative level...." *Coleman v. Dental Org. For Conscious Sedation*, LLC, 4:10CV798 TIA, 2010 WL 5146603 (E.D. Mo. Dec. 13, 2010) (quoting *Twombly*, 550 U.S. at 555). Here, Redd has alleged that DePuy "sold and released into commercial distribution"

the Hip System, and specifically, the femoral stem. Redd has alleged that the Hip System was implanted and used in a manner reasonably anticipated. And she has alleged that the femoral stem was unreasonably dangerous due to inadequately low fatigue strength and limited ductility as well as an inadequate annealing process used during the stem's manufacture. For purposes of her failure to warn claim, Redd also alleges DePuy failed to warn or adequately warn of the risk of harm due to the inadequacies listed above. The foregoing allegations contain sufficient facts to satisfy the standard set forth in *Twombly*. Redd's allegations raise a reasonable expectation that discovery will reveal evidence of her claim. *Twombly*, 550 U.S. at 556.

DePuy cites *Gross v. Stryker*, 858 F. Supp. 466, 499 (W.D. Penn. 2012) in arguing that in order to successfully plead her strict liability claims, Redd was required to plead facts excluding other possible causes of her injury. However, in *Stryke*r, the Plaintiff, who was the recipient of a failed hip prosthetic, made a "claim based on *res ipsa loquitur*." *Id*. at 497. Because *res ipsa loquitur* is a doctrine that allows juries to infer negligence from the circumstances surrounding the injury, the Court found that Plaintiff was required to plead the absence of other responsible causes for his injury. *Id*. at 498-99. Redd's pleading is distinguishable from *Stryker* because she has not asserted any claim in *res ipsa loquitur*. As noted above, the

elements that a plaintiff is required to plead under Missouri law for a strict liability claim do not include the exclusion of other possible causes of the plaintiff's injury.

B. The Negligence Claims

Under Missouri law, "in an action for negligence, generally, a plaintiff must allege ultimate facts which if proven, show: (1) the existence of a duty on the part of the defendant to protect the plaintiff from injury; (2) failure of the defendant to perform that duty; and (3) injury to the plaintiff resulting from such failure." *Menz v. New Holland N. Am., Inc.*, 460 F. Supp. 2d 1058, 1067 (E.D. Mo. 2006) *aff'd*, 507 F.3d 1107 (8th Cir. 2007). Thus, in order to recover on a claim for negligent manufacture, design or failure to warn, a plaintiff must establish that the defendant failed to use ordinary care to manufacture and/or design the product to be reasonably safe or to adequately warn of the risk of harm from the alleged defect. *Id*.

DePuy argues that Redd has failed to allege sufficient facts showing what warning was provided as to the Hip System or how it was inadequate. DePuy, as manufacturer of the Hip System, should already have notice of the contents of any existing product warnings. Furthermore, although Redd does not identify any particular warning language that she feels was missing or misleading, it is clear she is alleging that the warning was deficient as to the specific product defects or hazards described in the complaint. I find the level of detail Redd conveys in describing the

stem's alleged defects provides DePuy sufficient notice as to purported deficiencies in the Hip System's product warnings. *Cf. Bohnenstiehl v. Wright Medical Group, Inc.*, No. 4:13-CV-853 (CEJ), 2014 WL 319652, at *3 (E.D. Mo. Jan. 29, 2014) (denying defendant's motion to dismiss plaintiff's failure-to-warn claims despite defendant's argument that plaintiff was required to allege what warnings were given and how they were deficient).

DePuy further argues that Redd "does not allege any facts tending to make it plausible that DePuy had or should have had" knowledge that the design and manufacturing characteristics of the femoral stem created a premature risk of it breaking. However, Redd alleges that DePuy manufactured and designed the femoral stem, which makes it plausible that DePuy had or should have had knowledge of any design or manufacturing defects.

Finally, DePuy claims Redd's pleading is insufficient as to both of her failure to warn claims because she has failed to allege facts sufficient to show that the learned intermediary doctrine does not bar them. The learned intermediary doctrine provides that a drug manufacturer has a duty to warn a physician of the risks involved with its product. The physician then acts as a "learned intermediary" between the manufacturer and the physician's patient so that any warning given to the physician is deemed a warning to the patient. *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th

Cir. 1985); *Doe v. Alpha Therapeutic Corp*., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999). Under the learned intermediary doctrine, a manufacturer's inadequate warning to a physician is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that an adequate warning would have communicated. *Alpha Therapeutic Corp*., 3 S.W. 3d at 420.

DePuy claims Redd was required, in her initial pleading, to allege facts tending to show her doctor's knowledge (or lack thereof) regarding the alleged defect in order to defeat the learned intermediary doctrine. However, none of the cases cited by DePuy support this assertion.[5] Even assuming that the learned intermediary doctrine applies in this instance, Redd was not required to plead facts tending to negate it in order to survive a motion to dismiss.

Ultimately, the facts Redd alleges in her complaint give DePuy fair notice of what Redd's claims are and the grounds upon which they rest. *See Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (citing *Twombly*, 550 U.S. at 555). Therefore, DePuy's motion to dismiss Redd's claims for failure to state a plausible claim for relief is denied.

Accordingly,

[5] A review of cases discussing Missouri's learned intermediary doctrine indicates that it is typically asserted by a defendant as an affirmative defense to a failure to warn claim. *See, e.g., Alpha Therapeutic Corp*., 3 S.W.3d at 418-421; *Stanger v. Smith & Nephew, Inc.*, 401 F. Supp. 2d 974, 984 (E.D. Mo. 2005); *Wright v. American Home Products Corp*., No. 06-CV-4183-NKL, 2008 WL 1820902 at *3 (W.D. Mo. April 18, 2008).

IT IS HEREBY ORDERED that the defendant's motion to dismiss [#11] is **DENIED**.

IT IS FURTHER ORDERED that plaintiff's motion to file supplemental memorandum of law in opposition to defendant's motion to dismiss [#17] is **DENIED**.

This case will be set for a Rule 16 Scheduling Conference by separate Order.

CATHERINE D. PERRY
UNITED STATES DISTRICT JUDGE

Dated this 8th day of September, 2014.